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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 10/090,968 | 03/05/2002 | Richard B. Streeter | VIA-17 | 7502 |
| 7590 Pandiscio & Pandiscio 470 Totten Pond Road Waltham, MA 02154 | | | EXAMINER PELLEGRINO, BRIAN E | |
| | | | ART UNIT 3738 | PAPER NUMBER |
| DATE MAILED: 02/08/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/090,968 | COHN ET AL. | |
| | Examiner | Art Unit | |
| | Brian E Pellegrino | 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12/15/05</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "distal and proximal end collars" must be shown or the feature(s) canceled from the claim(s). A "collar" is something that surrounds a portion of another object. The drawings show distal and proximal sections that are **connected** to the rest of the body of the elongate body, not surrounding anything. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the written disclosure does not describe the distal or proximal end sections comprising "collars". The specification also fails to describe a "collar" with a "fixed length" and a "fixed diameter"

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is noted that the Applicants describe a proximal and distal end section for the elongate body, but fail to describe the body including a collar. According to the Examiner's understanding of a collar, it is something that surrounds a portion of an object or thing. The disclosure does not support this term. Additionally, the disclosure does not support the limitation that the "collar" has a "fixed diameter". If the elongate body shortens as expansion occurs, the "collar" should also change in its diameter.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojeibane (5911732) in view of Euteneuer (5681345). Hojeibane shows (Fig. 3) a bendable elongated body with at least two spring segment **5** connecting proximal and distal ends. Hojeibane also discloses that the spring segments or connectors can be elastic or of shape memory material, col. 7, lines 7,8,13,14,40. Hojeibane additionally discloses the elongate body is expandable to a second configuration, col. 5, lines 10,11. Upon expansion it is inherent that the length is shorter for the spring segments than its

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first length. However, Hojeibane does not disclose that there is a plurality of barbs on fixed length sections of the proximal and distal ends. Euteneuer teaches (Fig. 10) a collar with fixed length and diameter sections at the proximal and distal ends of the elongate body and contain barbs **34**. Euteneuer also teaches that the barbs are used for securing a sleeve on the stent, col. 6, lines 25-27. Euteneuer additionally teaches that the sleeve is advantageous in that it allows for cellular ingrowth and better securement of the stent device, col. 8, lines 5-17. It would have been obvious to one of ordinary skill in the art to incorporate the barbed proximal and distal end sections with a sleeve as taught by Euteneuer with the stent of Hojeibane such that it enables the device to be better anchored through the use of natural occurring body material in the form of a sleeve.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hojeibane '732 in view of Euteneuer '345 as applied to claim 4 above, and further in view of Solem et al. '432. Hojeibane as modified by Euteneuer is explained supra. However, Hojeibane in view of Euteneuer fail to disclose barbs on an intermediate section of the elongate body. Solem et al. teach (Fig. 3) that the intermediate section of the stent includes barbs **10**. It would have been obvious to one of ordinary skill in the art to incorporate barbs also on the intermediate section as taught by Solem with the stent of Hojeibane as modified by Euteneuer such that it further limits the stent from movement or dislodges from the target site it was implanted.

Claim 12 is rejected as best understood under 35 U.S.C. 103(a) as being unpatentable over Solem et al. '432 in view of Hojeibane '732. Solem et al. disclose a

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method of reducing mitral regurgitation by placing a prosthesis into the coronary sinus to reduce the gap between leaflets, col. 4, lines 19-21,38,39. Solem also discloses the device is made of a shape memory alloy (col. 3, lines 38-41) which inherently enables the device to transform from a first configuration to a second configuration. It can be seen (Fig. 3) the device is a spring-like structure with barbs that extend from end to end. However, Solem does not disclose that there are fixed length sections at the proximal and distal ends. Hojeibane teaches Fig. 3) a stent having spring sections between tubular support sections or "collars". It would have been obvious to one of ordinary skill in the art to incorporate the proximal and distal end collars as taught by Hojeibane with the stent of Solem such that it provides more radial support to the patient's vessel.

Response to Arguments

Applicant's arguments with respect to claims 1 and 12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (571) 272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

Brian E. Pellegrino
BRIAN E. PELLEGRINO
PRIMARY EXAMINER